(2) *pH.* Proceed as directed in §436.202 of this chapter, using the undiluted sample.

[39 FR 19149, May 30, 1974, as amended at 48 FR 3960, Jan. 28, 1983; 50 FR 19921, May 13, 1985]

### §452.175c Troleandomycin for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Troleandomycin for oral suspension is troleandomycin with suitable buffers, dispersants, preservatives, colorings, and flavorings. When the suspension is prepared as directed in its labeling, each milliliter contains 25 milligrams of troleandomycin. However, if it is for pediatric use, each milliliter contains 100 milligrams of troleandomycin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of troleandomycin that it is represented to contain. Its loss on drying is not more than 2 percent. The pH of the suspension, when prepared as directed in its labeling, is not less than 5.0 and not more than 7.0. The troleandomycin used conforms to the standards prescribed by §452.75(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The troleandomycin used in making the batch for potency, loss on drying, pH, residue on ignition, identity, $R_f$ value, acetyl value (only if more than one spot is present in the determination of $R_f$ value), and crystallinity.

(*b*) The batch for potency, loss on drying, and pH.

(ii) Samples required:

(*a*) The troleandomycin used in making the batch: 10 packages, nine containing approximately equal portions of not less than 500 milligrams and one containing not less than 2 grams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in §436.106 of this chapter, preparing the sample for assay as follows: Reconstitute the drug as directed in the labeling. Dilute an accurately measured representative portion of the sample with sufficient 80 percent isopropyl alcohol solution (solution 15) to obtain a stock solution containing 1,000 micrograms of troleandomycin per milliliter (estimated). Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 25 micrograms of troleandomycin per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

(3) *pH.* Proceed as directed in §436.202 of this chapter, using the suspension obtained after reconstituting the drug as directed in its labeling.

[39 FR 19149, May 30, 1974, as amended at 48 FR 3960, Jan. 28, 1983; 50 FR 19921, May 13, 1985]

### §452.175d Troleandomycin chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Each troleandomycin chewable tablet contains an amount equivalent to 125 milligrams of troleandomycin with suitable diluents, binders, buffers, colorings, and flavorings. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of troleandomycin that it is represented to contain. The loss on drying is not more than 5 percent. The troleandomycin used conforms to the standards prescribed by §452.75(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The troleandomycin used in making the batch for potency, loss on drying, pH, residue on ignition, identity, $R_f$ value, acetyl value (only if more than one spot is present in the determination of $R_f$ value), and crystallinity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The troleandomycin used in making the batch: 10 packages, nine containing approximately 500 milligrams each and one containing approximately 2 grams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar with sufficient 80 percent isopropyl alcohol solution (solution 15) to obtain a stock solution containing 1,000 micrograms of troleandomycin per milliliter (estimated). Blend 3 to 5 minutes. Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 25 micrograms of troleandomycin per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

[39 FR 19149, May 30, 1974, as amended at 48 FR 3960, Jan. 28, 1983; 48 FR 36571, Aug. 12, 1983; 50 FR 19921, May 13, 1985]

## Subpart C—Injectable Dosage Forms

### § 452.225 Erythromycin ethylsuccinate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin ethylsuccinate injection is erythromycin ethylsuccinate and butylaminobenzoate dissolved in polyethylene glycol 400. It contains a suitable and harmless preservative. Each milliliter contains 50 milligrams of erythromycin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of erythromycin that it is represented to contain. It contains 2 percent butylaminobenzoate. It is sterile. Its moisture content is not more than 1.5 percent. The erythromycin ethylsuccinate used conforms to the standards prescribed therefore by § 452.25a(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, each immediate container shall bear on its label and labeling the statement: ''Warning—For intramuscular use only''.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin ethylsuccinate used in making the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency, sterility, and moisture.

(ii) Samples required:

(*a*) The erythromycin ethylsuccinate used in making the batch: 10 packages, each containing 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation, except that if the product is sterilized after filling, a representative sample consisting of 10 immediate containers from each sterilizer load. If only one sterilizer load is involved, the sample shall consist of 20 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: By means of a suitable hypodermic needle and syringe, remove an accurately measured representative volume of the sample and dilute with sufficient methyl alcohol to give a solution containing 1.0 milligram of erythromycin base per milliliter (estimated). Further dilute with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except use a bacterial-retentive membrane resistant to the solvent polyethylene glycol 400 and add 1 milliliter from each immediate container directly to the membrane, thus eliminating the preliminary solubilization step.

(3) [Reserved]